

Program Requirements Document Companywide	18.1 QUALITY ASSURANCE INTERNAL AND EXTERNAL AUDITS	Identifier: PRD-5089 Revision: 3 Page: 1 of 9
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Manual: 13A—Quality and Requirements
Management Program Documents

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1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for external and internal quality assurance *audits* (see def.). See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to company organizations involved in the performance of QA audits.

3. RESPONSIBILITIES

3.1 Independent Oversight Organization

The independent oversight organization is responsible for:

- A. Conducting audits using personnel qualified/certified per PRD-5073, 2.3 Auditor/Lead Auditor Qualification and Certification.
- B. Implementing an effective audit program.
- C. Developing and distributing audit schedules.
- D. Ensuring implementation of *corrective actions* (see def.) is verified.

3.2 Audited Organizations

Audited organizations are responsible for:

- A. Providing audit personnel with reasonable and timely access to the facilities, documents, and personnel needed for planning and performing audits.
- B. Evaluating findings reported on audit reports for reportability to the Department of Energy.
- C. Providing responses to findings that describe the actions taken (or planned) in order to correct the problem and prevent recurrence.
- D. Providing for access by *auditor(s)/lead auditor* (see defs.) to appropriate levels of management to ensure resolution of audit findings.

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- E. Implementing corrective actions within specified time frames identified in responses to findings.

3.3 Procurement Organization

The procurement organization is responsible for:

- A. Establishing and maintaining a site wide schedule for all required external *supplier* (see def.) audits.
- B. Performing external supplier audits to evaluate supplier conformance with approved contractual requirements.
- C. Establishing and implementing a supplier qualification and/or requalification process.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 Basic

- 4.1.1.1 Audits shall be performed to *verify* (see def.) that performance criteria are met and to determine the effectiveness of the program. *[NQA-1-1997, Requirement 18, 100 1s]*
- 4.1.1.2 The lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions *[NQA-1-1997, Requirement 2, 303 1s]*

4.1.2 Scheduling Internal Audits

- 4.1.2.1 Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with on-going work. *[DOE/RW-0333P 18.2.1.A; NQA-1-1997, Requirement 18, 200 1s]*
- 4.1.2.2 Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work. *[DOE/RW-0333P 18.2.1.B; NQA-1-1997, Requirement 18, 200 1s]*
- 4.1.2.3 Internal audits shall be scheduled to begin as early in the life of the work as practical, and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. *[DOE/RW-0333P 18.2.1.C]*

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- 4.1.2.4 Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.
[DOE/RW-0333P 18.2.1.D; NQA-1-1997, Requirement 18, 200 2s]
- 4.1.2.5 Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.
[DOE/RW-0333P 18.2.1.F]

4.1.3 Scheduling External Audits

- 4.1.3.1 The need for and frequency of external audits shall be determined after the supplier has been selected to perform work. The determination shall be based on the complexity and nature of the *items* (see def.) or *services* (see def.) being procured. *[DOE/RW-0333P 18.2.2.A.1s and 18.2.2.A.2s]*
- 4.1.3.2 External audits shall not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, or adaptable to standard or automated *inspections* (see def.) or *tests* (see def.) of the end item to verify quality characteristics after delivery. The rationale for not performing audits for these items shall be documented. *[DOE/RW-0333P 18.2.2.B.1s and 18.2.2.B.2s]*
- 4.1.3.3 The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs. *[DOE/RW-0333P 18.2.2.G]*
- 4.1.3.4 The audit schedule shall be developed annually and revised periodically to ensure that coverage is maintained current.
[DOE/RW-0333P 18.2.3]

4.1.4 Audit Plan

- 4.1.4.1 The auditing organization shall develop and document an audit plan for each scheduled audit. *[NQA-1-1997, Requirement 18, 301 1s; DOE/RW-0333P 18.2.4.A.1s]*
- 4.1.4.2 The audit plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. *[NQA-1-1997, Requirement 18, 301 2s; DOE/RW-0333P 18.2.4.A.2s]*

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- 4.1.4.3 Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items. *[DOE/RW-0333P 18.2.4.A.3s]*
- 4.1.4.4 The scope of each audit shall be based on evaluation of implementing documents, activities, and items to be audited, the results of previous audits, and the impact of significant changes in personnel, organization, or the QA program. *[DOE/RW-0333P 18.2.4.B]*

4.1.5 Audit Team Independence

- 4.1.5.1 Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. *[NQA-1-1997, Requirement 18, 100 2s; DOE/RW-0333P 18.2.5.1s]*
- 4.1.5.2 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. *[NQA-1-1997, Requirement 18, 302; DOE/RW-0333P 18.2.5.2s]*

4.1.6 Selection of the Audit Team

- 4.1.6.1 An audit team shall be identified prior to the beginning of each audit. *[NQA-1-1997, Requirement 18, 303 1s; DOE/RW-0333P 18.2.6.A.1s]*
- 4.1.6.2 The audit team shall include representatives from the QA organization, and when appropriate, applicable technical organizations. *[DOE/RW-0333P 18.2.6.A.2s]*
- 4.1.6.3 The audit team shall contain one or more auditors, one being designated the lead auditor who supervises the team, organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. *[DOE/RW-0333P 18.2.6.B; NQA-1-1997, Requirement 18, 303 2s; NQA-1-1997, Requirement 2, 303 1s]*
- 4.1.6.4 Lead auditors and auditors shall be qualified in accordance with the requirements of PRD-5073, 2.3 Auditor/Lead Auditor Qualification and Certification. *[DOE/RW-0333P 18.2.6.C]*
- 4.1.6.5 *Technical specialists* (see def.) may be used by the auditing organization to assist in assessing the adequacy of technical processes. *[DOE/RW-0333P 18.2.6.D.1s]*

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- 4.1.6.6 Technical specialists, when used, shall be indoctrinated, trained and qualified in accordance with the requirements of PRD-5072, 2.2 Personnel Training and Qualification, and PRD-5073, 2.3 Auditor/Lead Auditor Qualification and Certification. *[DOE/RW-0333P 18.2.6.D.2s]*
- 4.1.6.7 In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team. *[DOE/RW-0333P 18.2.6.E]*
- 4.1.6.8 The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or *training* (see def.) commensurate with the scope, complexity, or special nature of the work to be audited. *[DOE/RW-0333P 18.2.6.F]*

4.1.7 Performing Audits

- 4.1.7.1 The audit team leader shall ensure that the audit team is prepared before starting the audit. *[DOE/RW-0333P 18.2.7.A]*
- 4.1.7.2 Audits shall be performed in accordance with written procedures or checklists. *[DOE/RW-0333P 18.2.7.B]*
- 4.1.7.3 Elements selected for audit shall be evaluated against specified requirements. *[NQA-1-1997, Requirement 18, 400 1s; DOE/RW-0333P 18.2.7.C]*
- 4.1.7.4 *Objective evidence* (see def.) shall be examined to the depth necessary to determine if these elements are being implemented effectively. *[NQA-1-1997, Requirement 18, 400 2s; DOE/RW-0333P 18.2.7.D]*
- 4.1.7.5 Audit results shall be documented and reported to and reviewed by *responsible managers* (see def.). *[NQA-1-1997, Requirement 18, 100 3s; DOE/RW-0333P 18.2.7.E.1s]*
- 4.1.7.6 Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. *[NQA-1-1997, Requirement 18, 400 3s; DOE/RW-0333P 18.2.7.E.2s]*
- 4.1.7.7 Identified *conditions adverse to quality* (see def.) shall be documented and corrected in accordance with PRD-5087, 16.1 Corrective Action. *[DOE/RW-0333P 18.2.7.F]*
- 4.1.7.8 Nonconforming items identified during an audit shall be controlled by the audited organization in accordance with PRD-5086, 15.1 Control of Nonconforming Items. *[DOE/RW-0333P 18.2.7.G]*

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4.1.8 Reporting

- 4.1.8.1 The audit report shall be signed or otherwise endorsed by the lead auditor and issued to the audited organization and impacted organizations. *[NQA-1-1997, Requirement 18, 500 1s; DOE/RW-0333P 18.2.8.1s]*
- 4.1.8.2 The audit report shall *[NQA-1-1997, Requirement 18, 500 2s; DOE/RW-0333P 18.2.8.2s]*:
- A. Describe the audit scope. *[NQA-1-1997, Requirement 18, 500 (a); DOE/RW-0333P 18.2.8.A]*
 - B. Identify auditors and persons contacted. *[NQA-1-1997, Requirement 18, 500 (b); DOE/RW-0333P 18.2.8.B and 18.2.8.C]*
 - C. Summarize audit results, documents reviewed, persons interviewed, including a statement on the effectiveness of the elements audited. *[NQA-1-1997, Requirement 18, 500 (c); DOE/RW-0333P 18.2.8.D and 18.2.8.E]*
 - D. Describe each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. *[NQA-1-1997, Requirement 18, 500 (d); DOE/RW-0333P 18.2.8.F]*

4.1.9 Response

- 4.1.9.1 Management of the audited organization or activity shall investigate adverse audit findings, determine and schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of the actions taken or planned. *[NQA-1-1997, Requirement 18, 600 1s; DOE/RW-0333P 18.2.9]*
- 4.1.9.2 The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization in accordance with the requirements of PRD-5087, 16.1 Corrective Action. *[DOE/RW-0333P 18.2.10; NQA-1-1997, Requirement 18, 600 2s]*

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4.1.10 Follow-Up Action

- 4.1.10.1 Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with the requirements of PRD-5087, 16.1 Corrective Action. *[DOE/RW-0333P 18.2.11; NQA-1-1997, Requirement 18, 100 4s and 700]*

4.1.11 Records

- 4.1.11.1 All records designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. *[Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]*
- 4.1.11.2 Audit records shall include audit plans, audit reports, written responses, and the record of completion of corrective action. *[NQA-1-1997, Requirement 18, 800]*

4.2 Specific Requirements for DOE/RW-0333P QARD Revision 10 Applications

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the Spent Nuclear Fuel Program.

4.2.1 Scheduling Internal Audits

- 4.2.1.1 Internal audits of work to verify QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter. *[DOE/RW-0333P 18.2.1.E]*

4.2.2 Scheduling External Audits

- 4.2.2.1 External audits for compliance shall be performed triennially, as a minimum, with the initial audit to occur as early in the life of the activity as practical. *[DOE/RW-0333P 18.2.2.C]*
- 4.2.2.2 Pre-award surveys, if applicable, may serve as the first triennial audit, provided *[DOE/RW-0333P 18.2.2.D]*:
- A. The supplier is implementing the same QA program for other contracts that is proposed for the *purchasers* (see def.) contract, and *[DOE/RW-0333P 18.2.2.D.1]*

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- B. The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.
[DOE/RW-0333P 18.2.2.D.2]

- 4.2.2.3 External audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.
[DOE/RW-0333P 18.2.2.E]

- 4.2.2.4 Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. The evaluation shall be documented and based on
[DOE/RW-0333P 18.2.2.F.1s and 18.2.2.F.2s]:

- A. Review of documentation furnished by the supplier (such as certificates of conformance, nonconformance notices, and corrective actions). [DOE/RW-0333P 18.2.2.F.1]
- B. Results of previous source *verifications* (see def.) audits, *management assessments* (see def.), and receiving inspections, including audits from other sources.
[DOE/RW-0333P 18.2.2.F.2]
- C. Operating experience of identical or similar work furnished by the same supplier. [DOE/RW-0333P 18.2.2.F.3]
- D. A review of *procurement documents* (see def.) to determine what additional work the supplier has received since the initial contract. [DOE/RW-0333P 18.2.2.F.4]

5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

audit

auditors

condition adverse to quality

corrective action

inspection

item

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lead auditor

management assessments

objective evidence

procurement document

purchaser

quality assurance record

responsible manager

services

supplier

technical specialist

test

training

verification

verify

6. REFERENCES

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

7. APPENDICES

Appendix A, 18.1 Basis

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APPENDIX A

18.1 Basis

Source	Citation	Requirement	Comments
NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 2	303 1s	4.1.6.3	Consensus Requirement (CR)
ASME NQA-1-1997, Requirement 18	100 1s	4.1.1.1	CR
NQA-1-1997, Requirement 18	100 2s	4.1.5.1	CR
NQA-1-1997, Requirement 18	100 3s	4.1.7.5	CR
NQA-1-1997, Requirement 18	100 4s	4.1.10.1	CR
NQA-1-1997, Requirement 18	200 1s	4.1.2.1	CR
NQA-1-1997, Requirement 18	200 1s	4.1.2.2	CR
NQA-1-1997, Requirement 18	200 2s	4.1.2.4	CR
NQA-1-1997, Requirement 18	301 1s	4.1.4.1	CR
NQA-1-1997, Requirement 18	301 2s	4.1.4.2	CR
NQA-1-1997, Requirement 18	302	4.1.5.2	CR
NQA-1-1997, Requirement 2	303 1s	4.1.1.2	CR
NQA-1-1997, Requirement 18	303 1s	4.1.6.1	CR
NQA-1-1997, Requirement 18		4.1.6.3	CR
NQA-1-1997, Requirement 18	400 1s	4.1.7.3	CR
NQA-1-1997, Requirement 18	400 2s	4.1.7.4	CR
NQA-1-1997, Requirement 18	400 3s	4.1.7.6	CR
NQA-1-1997, Requirement 18	500 (a)	4.1.8.2.A	CR
NQA-1-1997, Requirement 18	500 (b)	4.1.8.2. B	CR
NQA-1-1997, Requirement 18	500 (c)	4.1.8.2.C	CR
NQA-1-1997, Requirement 18	500 (d)	4.1.8.2.D	CR
NQA-1-1997, Requirement 18	500 1s	4.1.8.1	CR
NQA-1-1997, Requirement 18	500 2s	4.1.8.2	CR
NQA-1-1997, Requirement 18	600 1s	4.1.9.1	CR
NQA-1-1997, Requirement 18	600 2s	4.1.9.2	CR
NQA-1-1997, Requirement 18	700	4.1.10.1	CR
NQA-1-1997, Requirement 18	800	4.1.11.2	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	18.2.1.A	4.1.2.1	CR
DOE/RW-0333P	18.2.1.B	4.1.2.2	CR
DOE/RW-0333P	18.2.1.C	4.1.2.3	CR
DOE/RW-0333P	18.2.1.D	4.1.2.4	CR
DOE/RW-0333P	18.2.1.E	4.2.1.1	Specific Requirement (SR)
DOE/RW-0333P	18.2.1.F	4.1.2.5	CR

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APPENDIX A

18.1 Basis

Source	Citation	Requirement	Comments
DOE/RW-0333P	18.2.10	4.1.9.2	CR
DOE/RW-0333P	18.2.11	4.1.10.1	CR
DOE/RW-0333P	18.2.2.A.1s and 18.2.2.A.2s	4.1.3.1	CR
DOE/RW-0333P	18.2.2.B.1s and 18.2.2.B.2s	4.1.3.2	CR
DOE/RW-0333P	18.2.2.C	4.2.2.1	SR
DOE/RW-0333P	18.2.2.D	4.2.2.2	SR
DOE/RW-0333P	18.2.2.D.1	4.2.2.2.A	SR
DOE/RW-0333P	18.2.2.D.2	4.2.2.2.B	SR
DOE/RW-0333P	18.2.2.E	4.2.2.3	SR
DOE/RW-0333P	18.2.2.F.1	4.2.2.4.A	SR
DOE/RW-0333P	18.2.2.F.1s and 18.2.2.F.2s	4.2.2.4	SR
DOE/RW-0333P	18.2.2.F.2	4.2.2.4.B	SR
DOE/RW-0333P	18.2.2.F.3	4.2.2.4.C	SR
DOE/RW-0333P	18.2.2.F.4	4.2.2.4.D	SR
DOE/RW-0333P	18.2.2.G	4.1.3.3	CR
DOE/RW-0333P	18.2.3	4.1.3.4	CR
DOE/RW-0333P	18.2.4.A.1s	4.1.4.1	CR
DOE/RW-0333P	18.2.4.A.2s	4.1.4.2	CR
DOE/RW-0333P	18.2.4.A.3s	4.1.4.3	CR
DOE/RW-0333P	18.2.4.B	4.1.4.4	CR
DOE/RW-0333P	18.2.5.1s	4.1.5.1	CR
DOE/RW-0333P	18.2.5.2s	4.1.5.2	CR
DOE/RW-0333P	18.2.6.A.1s	4.1.6.1	CR
DOE/RW-0333P	18.2.6.A.2s	4.1.6.2	CR
DOE/RW-0333P	18.2.6.B	4.1.6.3	CR
DOE/RW-0333P	18.2.6.C	4.1.6.4	CR
DOE/RW-0333P	18.2.6.D.1s	4.1.6.5	CR
DOE/RW-0333P	18.2.6.D.2s	4.1.6.6	CR
DOE/RW-0333P	18.2.6.E	4.1.6.7	CR
DOE/RW-0333P	18.2.6.F	4.1.6.8	CR
DOE/RW-0333P	18.2.7.A	4.1.7.1	CR
DOE/RW-0333P	18.2.7.B	4.1.7.2	CR
DOE/RW-0333P	18.2.7.C	4.1.7.3	CR
DOE/RW-0333P	18.2.7.D	4.1.7.4	CR

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APPENDIX A

18.1 Basis

Source	Citation	Requirement	Comments
DOE/RW-0333P	18.2.7.E.1s	4.1.7.5	CR
DOE/RW-0333P	18.2.7.E.2s	4.1.7.6	CR
DOE/RW-0333P	18.2.7.F	4.1.7.7	CR
DOE/RW-0333P	18.2.7.G	4.1.7.8	CR
DOE/RW-0333P	18.2.8.1s	4.1.8.1	CR
DOE/RW-0333P	18.2.8.2s	4.1.8.2	CR
DOE/RW-0333P	18.2.8.A	4.1.8.2.A	CR
DOE/RW-0333P	18.2.8.B and 18.2.8.C	4.1.8.2. B	CR
DOE/RW-0333P	18.2.8.D and 18.2.8.E	4.1.8.2.C	CR
DOE/RW-0333P	18.2.8.F	4.1.8.2.D	CR
DOE/RW-0333P	18.2.9	4.1.9.1	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.11.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements